PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference SHAL3.0-032/	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/US04/24183	International filing date *(day/month/year)* 26 July 2004 (26.07.2004)	Priority date *(day/month/year)* 05 August 2003 (05.08.2003)
International Patent Classification (IPC) or national classification and IPC IPC: A61K 38/00(2006.01) USPC: 514/2;930/120		
Applicant THE ADMINISTRATORS OF THE TULANE EDUCATIONAL FUND		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 9 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *(sent to the applicant and to the International Bureau)* a total of ___ sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) ____ , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☒	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand 16 February 2005 (16.02.2005)	Date of completion of this report 27 April 2006 (27.04.2006)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Valerie Bell-Harris for B. Dell Chism Telephone No. (571) 272-1600

Form PCT/IPEA/409 (cover sheet)(April 2005)

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Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4(a))

☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☒ the description:
pages 1-90 as originally filed/furnished
pages* NONE received by this Authority on
pages* NONE received by this Authority on

☒ the claims:
pages 91-104 as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* NONE received by this Authority on
pages* NONE received by this Authority on

☐ the drawings:
pages NONE as originally filed/furnished
pages* NONE received by this Authority on
pages* NONE received by this Authority on

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☒ The amendments have resulted in the cancellation of:

☒ the description, pages NONE
☒ the claims, Nos. NONE
☒ the drawings, sheets/figs NONE
☒ the sequence listing (*specify*): NONE
☒ any table(s) related to the sequence listing (*specify*): NONE

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages
☐ the claims, Nos.
☐ the drawings, sheets/figs
☐ the sequence listing (*specify*):
☐ any table(s) related to the sequence listing (*specify*):

** If item 4 applies, some or all of those sheets may be marked "superseded."*

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 3 and 4

because:

☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no international search report has been established for said claims Nos. 3 and 4

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees the applicant has, within the applicable time limit:

   ☐ restricted the claims.

   ☒ paid additional fees.

   ☐ paid additional fees under protest, and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☐ neither restricted the claims nor paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:

   ☐ complied with.

   ☒ not complied with for the following reasons:

Please See Continuation Sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts

   ☒ the parts relating to claims Nos. 1-2 and 5-28 (in part)

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-2 and 5-28 (in part)	YES
	Claims NONE	NO
Inventive Step (IS)	Claims 1-2 and 5-28 (in part)	YES
	Claims NONE	NO
Industrial Applicability (IA)	Claims 1-2 and 5-28 (in part)	YES
	Claims NONE	NO

2. Citations and Explanations (Rule 70.7)

Claims 1-2 and 5-28 (in part) meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the claimed peptide sequences of the first invention (as discussed in PCT/ISA 206) of claim 1, and peptides 30-42, 62-64, 84 and 85 claimed in, for example, claim 5.

Claims 1-2 and 5-28 (in part) the criteria set out in PCT Article 33(4), and thus claims 1-2 and 5-28 (in part) have industrial applicability because the subject matter claimed can be made or used in industry.

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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

The description is objected to as containing the following defects under PCT Rule 66.2(a)(iii) in the form or contents thereof: page 5, line 6, 1 in "Tyr1" should be superscripted.

Claims 6 and 8-28 are objected to under PCT Rule 66.2(a)(iii) as containing the following defects in the form or contents thereof: in claim 6, the period after "6" in the first line is misplaced; in claims 8-28, commas after "claims 1" should be deleted.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 15-21 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because the claims are not fully supported by the description (see PCT/ISA/237 Box No. VIII.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

IV. 3. This Authority considers that the requirement of unity of invention is accordance with Rules 13.1, 13.2 and 13.3 is not complied with for the following reasons:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-4, 8-14, and 22-28, drawn to the peptide of the formulae of claim 1, and pharmaceutically accepted salts thereof. Furthermore, the use of the peptide having the formulae recited in the instant claim 1 for the production of a pharmaceutical composition, and a pharmaceutically administrable composition consisting essentially of the peptide having the formulae recited in the instant claim 1.

Group II, claim(s) 5-7, 8-14 and 22-28, drawn to the peptide selected from the group consisting of sequences listed in the instant claims 5-7. Furthermore, the use of the peptide selected from the group consisting of sequences listed in the instant claims 5-7 for the production of a pharmaceutical composition, and a pharmaceutically administrable composition consisting essentially of the peptide selected from the group consisting of sequences listed in the instant claims 5-7.

Group III, claim(s) 15-21, drawn to the second process of using the peptide recited in Groups I and II for administering to a patient.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack of unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

R1 group, R2 group, and A0-A30 groups, as recited in claims 1-2. Furthermore, peptides 2-16, 21-22, 30-31, 33-43, 45-60, 62-65, 67-82 and 84-121 correspond to claims 3-7.

The following claim(s) are generic: 1-28.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature of the Group I claims is the claimed peptide sequence represented by the formula recited in claim 1 and a pharmaceutically acceptable salts thereof, these special features are not present in Group II as each of the sequences lack a core structure that is shared between them. As for Group III, 37 CFR 1.475 (d) states: If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and sect. 1.476(c). Two methods of use are claimed, the method of use of a compound of any claims 1 or 5 for the production of a pharmaceutical composition (claims 8-14), and the method of use by

Supplemental Box

administering to a patient a suppressive effective amount of a compound of any of claims 1 or 5 (claims 15-21). According to 37 CFR 1.475(d), the first method of use (claims 8-14) will be considered.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

There is no core sequence between the peptides, therefore, no common structure is present.